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10/692,011	10/24/2003	Kenji Nakajima	Q78108	8536

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EXAMINER	
LUM, LEON YUN BON	
ART UNIT	**PAPER NUMBER**
1641	

DATE MAILED: 10/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/692,011	NAKAJIMA, KENJI	
	Examiner	Art Unit	
	Leon Y Lum	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 September 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) *1,4,7,10 and 13-20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2,3,5,6,8,9,11 and 12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *24 October 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *20041004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with without traverse of Group II, claims 2-3, 5-6, 8-9, and 11-12 in the reply filed on 17 September 2004 is acknowledged.

Claim Objections

2. Claims 2-3, 5-6, 8-9, and 11-12 objected to because of the following informalities: The limitation wherein ligands or receptors are bound to porous adsorptive regions is repeated numerous times within each of the instant claims. For example, in claims 2-3, lines 4-5 recite "plurality of porous adsorptive regions, to which ligands or receptors have been bound respectively". Lines 12-13 of claims 2-3 again recite the same limitation wherein "ligands or receptors, each of which has been bound to one of the porous adsorptive regions". Lines 15-16 of claims 2-3 again recite "one of the ligands, each of which has been bound to one of the porous adsorptive regions". Lines 17-19 of claims 2-3 again recite "one of the receptors, each of which has been bound to one of the porous adsorptive regions". Claims 5-6, 8-9, and 11-12 recite similar phrases wherein the limitation of ligands and receptors bound to the porous adsorptive regions is repeated. Appropriate correction is required.

Specification

3. The abstract of the disclosure is objected to because lines 2 and 7 contain the legal terms "wherein". Correction is required. See MPEP § 608.01(b).

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 2-3, 5-6, 8-9, and 11-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6. In claims 2-3 (line 8), 5-6 (line 3), 8-9 (line 12), and 11-12 (line 15) the phrase "forcibly causing" is vague and indefinite.

With regards to claims 2-3, the specification does not provide a definition for the term and it is unclear what force causes the receptor and ligand (line 8) to flow.

With regards to claims 5-6, the specification does not provide a definition for the term and it is unclear what force causes the reaction liquid (line 3) to flow.

With regards to claims 8-9, the specification does not provide a definition for the term and it is unclear what force causes the reaction liquid (line 12) to flow.

With regards to claims 11-12, the specification does not provide a definition for the term and it is unclear what force causes the reaction liquid (line 15) to flow.

7. In claims 2-3, line 8 of the claims, the phrase "a receptor or a ligand" is vague and indefinite. It is not clear whether the receptor and ligand in the instant phrase is the same or different from the ligands and receptors recited in the preceding phrase "to which ligands or receptors have been bound" (lines 4-5).

8. In claims 2-3, the phrases "the receptor or the ligand" (line 9), "the receptor or the ligand" (line 11), "the ligands or the receptors" (line 12), "the receptor or the ligand" (line 14), "one of the ligands" (line 15), "one of the receptors" (line 17), "detecting the receptor or the ligand" (line 20), and "at least one of the ligands or at least one of the receptors" (lines 21-22) are vague and confusing. It is not clear whether the receptor and ligand in the instant phrases refer to the receptor and ligand in line 8 or to the ligands and receptors in lines 4-5, or to both.

9. In claims 2-3 (line 22 or the claims), 5-6 (line 21 of the claims), 8-9 (line 24 of the claims), and 11-12 (line 31 of the claims) the term "utilization" is vague and indefinite.

With regards to claims 2-3, the specification does not provide a definition for the term and it is unclear how the labeling substance (lines 22-23) is used.

With regards to claims 5-6, the specification does not provide a definition for the term and it is unclear how the labeling substance (lines 21-22) is used.

With regards to claims 8-9, the specification does not provide a definition for the term and it is unclear how the labeling body (lines 21-22) is used.

With regards to claims 11-12, the specification does not provide a definition for the term and it is unclear how the labeling substance (lines 31-32) is used.

10. In claims 2-3, line 28, the phrase "bubble removing process" is vague and indefinite. The specification does not provide a definition for the term and it is unclear what type of process is used for removing bubbles.

11. In claims 8-9, lines 3-4, the phrase "subjecting the receptor or the ligand to the specific binding with the ligands or the receptors" is vague and confusing. The instant phrase suggests that there are two sets of either ligands or receptors and that the two sets perform specific binding with each other. However, the parent claims 2-3 only recite one set of ligands or receptors (lines 4-5), and that the ligands or receptors are bound to the porous adsorptive regions. Therefore, it is confusing as to whether there are two sets of ligands or receptors, and in the case that there is only one set, how the ligands or receptors can perform specific binding if they are all immobilized onto a surface.

12. In claims 8-9, the phrases "the receptor or the ligand" (line 6), "at least one of the ligands" (line 7), "at least one of the receptors" (line 9), "the receptor or the ligand" (lines 16-17), "the ligands" (line 18), "the receptors" (line 20), "the receptor or the ligand" (line

23), "one of the ligands" (line 24), and "one of the receptors" (line 25) are vague and indefinite. It is unclear whether the ligands and receptors in the instant phrases are the receptors and ligands of line 3 of the instant claims, or if they are the receptors and ligands of line 4 of the instant claims.

13. In claims 11-12, lines 3-5, the phrase "auxiliary substance-bound receptor or an auxiliary substance-bound ligand, to which an auxiliary substance has been bound" is vague and confusing. The terms "auxiliary substance-bound receptor" and "auxiliary substance-bound ligand" indicate that the receptors and ligand are already bound to auxiliary substances. Therefore, it is unclear whether the term "auxiliary substance" in lines 4-5 refers to the auxiliary substances already bound to the receptors and ligands, or whether it is another auxiliary substance different from the ones bound to the receptors and ligands.

Claim Rejections - 35 USC § 102

14. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

15. Claims 2-3 and 5-6 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Besemer et al (US 6,140,044).

Besemer et al reference teaches an assay method using a biochemical analysis unit comprising the step of obtaining a biochemical analysis unit provided with a plurality of porous adsorptive regions, to which ligands have been bound respectively, by disclosing methods that provide a substrate having an array of probes that is attached to a cavity, wherein the substrate is a wafer that can be (poly)tetrafluoroethylene (column 1, lines 59-63; column 5, lines 41-63, especially lines 41-42 and 55-58; and Figure 1a).

Besemer et al reference also teaches the steps of performing a specific binding detecting process comprising the steps of forcibly causing a reaction liquid containing a labeled receptor, which has been labeled with a labeled receptor, to flow such that the reaction liquid flows across each of the porous adsorptive regions of the biochemical analysis unit provided with the plurality of the porous adsorptive regions, to which the ligands have been bound respectively, the labeled receptor being thus subjected to specific binding with the ligands, each of which has been bound to one of the porous adsorptive regions of the biochemical analysis unit, the labeled receptor being thereby specifically bound to at least one of the ligands, each of which has been bound to one of the porous adsorptive regions of the biochemical analysis unit, by disclosing that various fluids can be introduced into a housing containing a chip, wherein the chip is one component of the wafer, in order for the fluid to contact the probes on the chip for hybridization and binding (column 12, lines 49-57 and 61-63; Figures 1a-1b), wherein

the probes are ligands and the fluid contains targets that are receptors (column 3, line 50 to column 4, lines 14), and wherein the targets in hybridization can be labeled (column 1, lines 31-34).

Besemer et al reference also teaches detecting the labeled receptor, which has thus been specifically bound to at least one of the ligands, by the utilization of a labeling substance, by disclosing that after hybridization, imaging systems can be used to qualitatively analyze the reaction between the probes and targets (column 13, lines 12-23, especially lines 21-22).

Besemer et al reference also teaches the step of a liquid being forcibly caused to flow, such that the liquid flows across each of the porous adsorptive regions of the biochemical analysis unit, during the specific binding detecting process, wherein bubble removing processing for removing bubbles, which are present in the liquid, from the liquid is performed during the flowing of the liquid, by disclosing that various fluids can be introduced into a housing containing a chip, wherein the chip is one component of the wafer, in order for the fluid to contact the probes on the chip for hybridization and binding (column 12, lines 49-57 and 61-63; Figures 1a-1b), as stated above, and that locating inlets/outlets at the highest and lowest positions in the cavity facilitates the removal of bubbles from the cavity (column 8, lines 3-15, especially lines 13-15; and Figure 5c).

Claim Rejections - 35 USC § 103

16. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

17. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

18. Claims 8-9 and 11-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Besemer et al (US 6,140,044) in view of Bronstein et al (US 5,543,295).

Besemer et al reference has been disclosed above, and additionally teaches the step of subjecting an auxiliary substance-bound receptor to which an auxiliary substance has been bound, to the specific binding with the ligands, each of which has been bound to one of the porous adsorptive regions of the biochemical analysis unit, the auxiliary substance-bound receptor being thereby specifically bound to at least one of the ligands, each of which has been bound to one of the porous adsorptive regions of the biochemical analysis unit, by disclosing that targets may be attached, covalently or

noncovalently, to a binding member, either directly or via a specific binding substance (column 3, line 61 to column 4, line 1), wherein the targets bind to probes that can be proteins or nucleic acids (column 3, lines 50-60), and wherein the target labels can be an enzyme (column 1, lines 31-34).

However, Besemer et al reference fails to disclose the step of forcibly causing a reaction liquid containing a labeling substance, which is capable of undergoing specific binding with the auxiliary substance, to flow such that the reaction liquid flows across each of the porous adsorptive regions of the biochemical analysis unit, the labeling substance, which is capable of undergoing specific binding with the auxiliary substance, being thus specifically bound to the auxiliary substance-bound receptor having been specifically bound to at least one of the ligands, each of which has been bound to one of the porous adsorptive regions of the biochemical analysis unit.

Bronstein et al reference teaches the step of contacting a detectable substance with a solution containing an enzyme bonded to a substance having a specific affinity for the detectable substance, wherein a dioxetane having a group cleavable by the enzyme portion of the specific affinity-enzyme compound is added, wherein the enzyme cleaves the enzyme cleavable group on the dioxetane, causing the dioxetane to decompose into two carbonyl compounds, and wherein the chromophore to which the enzyme cleavable group had been bonded is thus excited and luminesces, in order to detect an antibody, antigen, or nucleic acid in a sample (column, 17, line 57 to column 18, line 18), and in order to provide water soluble reporter molecules for bioassays

(column 2, lines 12-24), wherein the step can be performed on a solid surface (column 5, line 29).

It would have been obvious to modify the method of Besemer et al with the step of contacting a detectable substance with a solution containing an enzyme bonded to a substance having a specific affinity for the detectable substance, wherein a dioxetane having a group cleavable by the enzyme portion of the specific affinity-enzyme compound is added, wherein the enzyme cleaves the enzyme cleavable group on the dioxetane, causing the dioxetane to decompose into two carbonyl compounds and the chromophore to which the enzyme cleavable group had been bonded is thus excited and luminesces, as taught by Bronstein et al, in order to detect an antibody, antigen, or nucleic acid in a sample and in order to provide water soluble reporter molecules for bioassays. One of ordinary skill in the art at the time of the invention would have had reasonable expectation of success in using the enzyme-linked specific binding method of Bronstein et al, in the method of Besemer et al, since Besemer et al teach an assay method wherein probes immobilized on solid surfaces can be hybridized with target molecules that are labeled with enzymes, and Bronstein et al teach a method of the same embodiment and using the enzymes by cleaving an enzyme-cleavable bond on a dioxetane label to produce a detectable signal.

Conclusion

19. No claims are allowed.

20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leon Y Lum whose telephone number is (571) 272-2878. The examiner can normally be reached on 8:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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